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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,787	04/04/2001	Maurice Zauderer	1821.0040001/EKS/TJS	2970
26111	7590	07/15/2004		EXAMINER
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/824,787	ZAUDERER ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 27 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
  - 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 38,81,84,119,121,123,158 and 163-166 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

Continuation of Disposition of Claims: Claims pending in the application are 38-45,47-51,53,56-66,68,69,74-78,80-82,84-89,91,92,94-104,106,107,112-116,118-121,123-128,130,133-143,145,146,151-155,157-159 and 163-209.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 47-51,53,54,56-66,68,69,74-78,80-82,85-89,91,92,94-104,106,107,112-116,118,120,124-128,130,133-143,145,146,151-155,157,159 and 167-209.

## **DETAILED ACTION**

### ***Response to Arguments and Amendments***

1. Claims 38-45, 47-51, 53, 56-66, 68-69, 74-78, 80-82, 84-89, 91, 92, 94-104, 106, 107, 112-116, 118-121, 123-128, 130, 133-143, 145, 146, 151-155, 157-159 and 163-209 are pending.

Claims 39-46, 54, 83, 122, 131, 156 and 160-162 have been canceled.

Claims 38, 84, 123, 163, 164 and 166 have been amended.

Claims 47-51, 53, 54, 56-66, 68, 69, 74-78, 80-82, 85-89, 91, 92, 94-104, 106, 107, 112-116, 118, 120, 124-128, 130, 133-143, 145, 146, 151-155, 157, 159 and 167-209, drawn to non-elected inventions are withdrawn from examination.

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166, which read on the elected species, nn. are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 33, lines 5, 6 and 10. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code, as well as review the entire specification for similar errors. See MPEP § 608.01.

***Claim Objections***

4. Claim 38 is objected to because of the following informalities:
  - (a) the word "of" has been repeated twice. Applicants should delete the duplicate word;
  - (b) Claim 163 is objected to because it depends from cancelled claims 39-46.

Appropriate correction is required.

***Information Disclosure Statement***

5. The Examiner acknowledges and appreciates Applicants submission of courtesy copies of documents not reviewed and denoted as so on the copy of the PTO-1449 mailed January 2004. The information disclosure statement (IDS) filed October 16, 2002 as Paper No. 15 was considered in its entirety by the Examiner and a copy of the IDS is mailed with the instant action.

***Sequence Compliance***

6. This application contains sequence disclosures on several pages and within several tables that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are requested to review the entire specification and amend it to include the sequence

identifiers ensuring that these added SEQ ID numbers are not new matter.

***Withdrawn Rejection***

***Claim Rejections - 35 USC § 112***

7. The rejection of claims 163 and 164 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn. Claims 160-162 have been cancelled.

***Maintained and New Grounds of Rejections***

***Claim Rejections - 35 USC § 112***

8. Claims 38, 81, 84, 119, 121 and 163-166 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 38 to include the recitation, "wherein said polypeptide is at least 95% identical to a fragment of C35 (SEQ ID NO: 2)" and claim 84 to include, "an additional amino acids". Applicants have not pointedly expressed where in the specification support can be found for these amendments. Applicants are advised to cite the page and line number where support is found for these phrases or delete the new matter.

9. The rejection of claims 38, 81, 84, 119, 121, 123, 158 and 163-166 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claims 39-46, 83, 122 and 160-162 have been cancelled.

Applicants assert that “[c]ompliance with the written description requirement does not require a patent [application] specification to describe exactly the claimed subject matter; rather, the specification must show the skilled artisan that the applicant invented what is claimed.” Applicants continue to reiterate the criteria for the written description requirement, as well as list sections of the specification that describe numerous species falling within the genus claimed including fusion proteins. These points of view have been carefully considered, as well as the sections of the specification pointed out by Applicants however they are not persuasive.

Claims 38, 81, 84, 119, 121, 123, 158 and 163-166 broadly claim an isolated polypeptide comprising at least one C35 peptide epitope defined as I-105 to V-113 of SEQ ID NO: 2, as well as a fusion polypeptide that comprises an isolated C35 peptide epitope defined as I-105 to V-113 of SEQ ID NO: 2 and additional amino acids. The written description in this instant case only sets forth polypeptide, SEQ ID NO: 2 consisting of 115 amino acid residues and including the defined epitope consisting of I-105 to V-113. The written description is not commensurate in scope with the claims drawn to arbitrary isolated polypeptides that possibly exist on the carboxy- and amino-terminus of the defined fragment/epitope, amino acids I-105 to V-113 of SEQ ID NO: 2.

Furthermore, a fusion protein comprising the defined C35 peptide epitope and undefined amino acid sequences, simply regarded as “additional amino acids” and inclusive of variants and mutants is not commensurate scope with the established written description.

At the time the application was filed Applicants only had possession of SEQ ID NO: 2 containing the amino acid epitope, I-105 to V-113 and not polypeptides that are analogs of SEQ ID NO:2 and fusion proteins. The fusion protein potentially contains at least 107 amino acids that have not been described. Likewise the polypeptide that comprises one C35 peptide epitope is surrounded by amino acids not described in the specification. The specification does not evidence the possession of all the possible variant and mutant polypeptides that could be or may not be capable of exhibiting activities of a wild type C35 polypeptide. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

9. The rejection of claims 38, 81, 84, 119, 121, 123, 158 and 163-166 under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained. The specification does not enable any person skilled in the art to which it pertains, or with

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which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claims 39-46, 83, 122 and 160-162 have been cancelled.

Applicants assert, "the claimed polypeptides and fusion proteins do not need to have the same function as a wild type C35 polypeptide. The claimed polypeptides and fusion proteins comprise CTL epitopes that are useful in diagnosis, prognostic testing, and treatment of C35-specific cancers." Applicants also assert that the specification provides examples that CTLs specific for a C35 epitope kill breast cancer cell. These points of view and arguments have been carefully considered but found unpersuasive.

The Examiner has reviewed specific passages of the specification as pointed out by Applicants have not found enabling disclosure supporting the use of the plethora of C35 polypeptides encompassed by the claims. The specification does not support provide sufficient guidance on how to make and use all of the claimed proteins in the specific applications of treating cancer and diagnosing cancer. Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acid or acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved and detailed knowledge of the ways in which the protein's structure relates to its function. The specification provides essentially no guidance as to which of the infinite possible choices is likely to be successful. Without such guidance, the changes which must be

made in the nucleic sequence that encodes the variants of SEQ ID NO: 2, which results in limited sequence identity and/or undefined substitutions is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue.

***Claim Rejections - 35 USC § 102***

10. The rejection of claims 38, 81, 84, 119, 121, 123, 158 are 163-166 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent application publication number US2002/0052308A1 (May 2, 2002) is maintained. Claims 39-46, 122, 160 and 161 have been cancelled.

Applicants assert that publication US2002/0052308A1 does not disclose the claimed invention and the examined epitope, I-105 to V-113 of SEQ ID NO: 2 is not apparent in the cited publication and request the withdrawal of the rejection. This argument has been considered but found unpersuasive.

Applicants were provided with a sequence alignment between Applicants' SEQ ID NO: 2 and the publication's SEQ ID NO: 966 with the action mailed August 27, 2003 as Paper number 22. Notwithstanding, a courtesy copy of the alignment is provided with this instant action. Sequence number 966 of U.S. Patent application publication # US2002/0052308A1 discloses an isolated polypeptide comprising a peptide epitope, I-121 to V-129 which is the same as Applicants' C35 peptide epitope, I-105 to V-113 of SEQ ID NO: 2. The disclosed C35 peptide epitope is comprised amongst 122 additional amino acids, which reads on Applicants' claimed fusion protein. Also

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disclosed is a pharmaceutical composition comprising the disclosed peptide epitope, see page 208, sections 0258-0260.

***Claim Rejections - 35 USC § 103***

11. The rejection of claims 38, 81, 84, 119, 121, 158 and 163-166 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent application publication number US2002/0052308A1 (May 2, 2002) is maintained. Claims 39-46, 83, 122 and 160-162 have been cancelled.

Applicants' arguments are the same as those presented in the maintained 102(e) rejection. These arguments are not persuasive and the rejection is maintained for the reasons of record and presented the paragraph above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER**

  
Alana M. Harris, Ph.D.  
June 30, 2004